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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,718	05/15/2007	Ernst V. Arnold	065611-0119	1962
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FOLEY AND LARDNER LLP			EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/588,718

Applicant(s)

ARNOLD ET AL.

Examiner

Darryl C. Sutton

Art Unit

4133

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 6, 37 and 49-51 drawn to a composition comprising a C-based diazeniumdiolate compound attached to one phenyl-containing polymer wherein said polymer comprises a polymer backbone and said phenyl is pendant from the backbone and wherein said compound is not an imidate or thioimidate, wherein said composition releases NO and does not generate nitrosamines under physiological conditions.

Group II, claim(s) 1, 2, 6, 37 and 49-51, drawn to a composition comprising a C-based diazeniumdiolate compound attached to one phenyl-containing polymer wherein said polymer comprises a polymer backbone and said phenyl is part of the backbone and wherein said compound is not an imidate or thioimidate, wherein said composition releases NO and does not generate nitrosamines under physiological conditions.

Group III, claim(s) 1-4, 6-14, 18-32, 37 and 49-51 drawn to a composition comprising a C-based diazeniumdiolate compound attached to at least one phenyl-containing polymer and having the formula of claim 3 wherein said polymer comprises a polymer backbone and said phenyl is pendant from the backbone and wherein said compound is not an imidate or thioimide and where R_1 is an ether.

Group IV, claim(s) 1-4, 6-13, 18-32, 37 and 49-51 drawn to a composition comprising a C-based diazeniumdiolate compound attached to at least one phenyl-containing polymer and having the formula of claim 3 wherein said polymer comprises a polymer backbone and said phenyl is pendant from the backbone and wherein said compound is not an imidate or thioimide and where R_1 is a cyano.

Group V, claim(s) 1-4, 6-13, 15, 18-32, 37 and 49-51 drawn to a composition comprising a C-based diazeniumdiolate compound attached to at least one phenyl-containing polymer and having the formula of claim 3 wherein said polymer comprises a polymer backbone and said phenyl is pendant from the backbone and wherein said compound is not an imidate or thioimide and where R_1 is a thioether.

Group VI, claim(s) 1-4, 6-13, 16-32, 37 and 49-51 drawn to a composition comprising a C-based diazeniumdiolate compound attached to at least one phenyl-containing polymer and having the formula of claim 3 wherein said polymer comprises a polymer

backbone and said phenyl is pendant from the backbone and wherein said compound is not an imide or thioimide and where R_1 is a non-enamine amine.

Group VII, claim(s) 1-3, 5, 6, 13, 14, 18-37 and 49-51 drawn to a composition comprising a C-based diazeniumdiolate compound attached to at least one phenyl-containing polymer and having the formula of claim 3 wherein said polymer comprises a polymer backbone and said phenyl is part of the backbone and wherein said compound is not an imide or thioimide and where R_1 is an ether.

Group VIII, claim(s) 1-3, 5, 6, 13, 18-37 and 49-51 drawn to a composition comprising a C-based diazeniumdiolate compound attached to at least one phenyl-containing polymer and having the formula of claim 3 wherein said polymer comprises a polymer backbone and said phenyl is pendant from the backbone and wherein said compound is not an imide or thioimide and where R_1 is a cyano.

Group IX, claim(s) 1-3, 5, 6, 13, 15, 18-37 and 49-51 drawn to a composition comprising a C-based diazeniumdiolate compound attached to at least one phenyl-containing polymer and having the formula of claim 3 wherein said polymer comprises a polymer backbone and said phenyl is pendant from the backbone and wherein said compound is not an imide or thioimide and where R_1 is a thioester.

Group X, claim(s) 1-3, 5, 6, 13, 16-37, 49-51 drawn to a composition comprising a C-based diazeniumdiolate compound attached to at least one phenyl-containing polymer and having the formula of claim 3 wherein said polymer comprises a polymer backbone and said phenyl is pendant from the backbone and wherein said compound is not an imidate or thioimidate and where R_1 is a non-enamine amine.

Group XI, claim(s) 38-40 drawn to a method for delivering bacteriostatic or bacteriocidal quantities of NO to mammalian tissue.

Group XII, claim(s) 41, 44-46 drawn to a method of reducing or eliminating a pathogen in stored human platelets.

Group XIII, claim(s) 42 and 43 drawn to a method of storing blood platelets that prevents platelet activation in a platelet suspension.

Group XIV, claim(s) 47 and 48 drawn to a method of treating an animal comprising introducing an effective amount of a pharmaceutical carrier and a nitric oxide-releasing composition.

Group XV, claim(s) 52 drawn to medical device wherein all the parts of the device comprises a nitric oxide-releasing polymer.

The inventions listed as Groups I-VI and Groups VII-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I-VI are drawn to compounds comprising a phenyl-containing polymer where the phenyl is pendant from the backbone, whereas Groups VII-X are drawn to compounds comprising a phenyl-containing polymer where the phenyl is part of the backbone.

The inventions listed as Groups XI and Groups XII, XIII, XIV and XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group XI drawn to delivering a bacteriostatic or bacteriocidal quantities of NO to mammalian tissue, whereas Group XII is drawn to reducing or eliminating pathogens in human platelets stored in a storage container. Group XIII is drawn to a method of storing blood platelets that prevents platelet activation, therefore Groups XI and XIII lack a common technical feature because one of ordinary skill would not reasonable expect the method of delivering a bacteriostatic or bacteriocidal quantity of NO to mammalian tissue to be the same as preventing platelet activation in a storage container. Group XIV is drawn to treating an animal, therefore Group XI and XIV lack a common technical feature because one of ordinary skill would not reasonably expect the method of delivering a bacteriostatic or bacteriocidal quantities of NO to mammalian tissue to be the same as treating an animal, since an animal is a much more complex organism than mammalian tissue or an organ.

The inventions listed as Groups XII and Groups XIII, XIV and XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group XII is drawn to reducing or eliminating pathogens in human platelets stored in a storage container, whereas Group XIII is drawn to a method of storing human platelets that prevents platelet activation, therefore Groups XII and XIII lack a common technical feature because one of ordinary skill would not reasonably expect the methods for reducing or eliminating pathogens from human platelets to be the same as preventing platelet activation. Group XIV is drawn to treating an animal, therefore Groups XII and XIV lack a common technical feature because one of ordinary skill would not reasonably expect the method of eliminating pathogens in stored human platelets to be the same as treating an animal. Group XV is drawn to a medical device, wherein the entire device comprises a nitric oxide-releasing polymer, therefore Groups XII and XV lack a common technical feature because one of ordinary skill would not reasonably expect the medical device to be used in storing human platelets so that pathogens are eliminated.

The inventions listed as Groups XIII and Groups XIV, and XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group XIII is drawn to a method of storing human platelets that prevents

platelet activation, whereas Group XIV is drawn to treating an animal. Groups XIII and XIV lack a common technical feature because one of ordinary skill would not reasonable expect a method of storing human platelets that prevents platelet activation to be the same as a method for treating an animal. Group XV is drawn to a medical device, wherein all of he device comprises a nitric oxide-releasing polymer, therefore Groups XIII and XV lack a common technical feature because on of ordinary skill would not reasonably expect the storage of human platelets that prevents platelet activation to be accomplished by the medical device.

The inventions listed as Groups XIV and Groups XV and XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group XIV is drawn to treating an animal with a nitric oxide-releasing polymeric composition and a pharmaceutical carrier, whereas Group XV is drawn to a medical device comprised completely of nitric oxide-releasing polymer. Groups XIV and XV lack a common technical feature because one of ordinary skill would not reasonable expect the medical device to release nitric oxide to treat the animal in the same way as the nitric oxide-releasing polymeric composition and a pharmaceutical carrier of the method of Group XIV.

The inventions listed as Groups I-X and XI-XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the

same or corresponding special technical features for the following reasons: Since the application contains distinct compositions Groups I-X, and distinct methods Groups XI-XV one of ordinary skill would not expect the distinct compositions to be able to perform the distinct methods in the same way as the methods are claimed in the instant application.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(a) moiety that is substituted on phenyl, (b) ether moiety, (c) R₂ (protecting group or counteraction) (d) polymer, (e) polymer 1 and polymer 2, (f) medical device, and (g) position of attachment of the C-based diazeniumdiolate on phenyl group.

If the applicant elects Groups I, III-V and XI-XV then an election of **each** of (a) moiety that is substituted on phenyl, (c) species of R₂, (d) polymer, (f) a medical device and (g) the position of the attachment of the C-based diazeniumdiolate to the phenyl group must also be made.

If the applicant elects Groups II, VII-X and XI-XV then an election of **each** of (a) moiety substituted on phenyl, (b) ether moiety, (c) R₂ (protecting group or counteraction), and **either** (d) polymer, or (e) polymer 1 and polymer 2, (f) a medical device and (g) the position of the attachment of the C-based diazeniumdiolate to the phenyl group must also be made.

Each substituent and its position on the elected species must be disclosed.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-52.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the moieties that can be substituted onto the phenyl group will impart specific characteristics to the compound; the ether moieties will impart specific characteristics to the compound; the protecting groups will serve to protect the molecule, while the counter ion can induce chemical reactions; each of the polymers is distinct and adds distinct characteristics to the molecule; the position of the attachment of the C-based diazeniumdiolate to the phenyl group can effect the function of the composition.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM-5:00PM EST and on Fr from 7:30AM-4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on M-Th from 8:00AM-4:00PM at (571)272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

DCS


ARDIN H. MARSCHER
SUPERVISORY PATENT EXAMINER